UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,069	01/18/2006	Kazuyuki Oku	OKU 12	3696

1444 7590 10/19/2007

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
ISSAC, ROY P	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,069	OKU ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 7/30/2007, wherein claims 1-12 have been cancelled and claims 13-14 have been amended, and claims 15-22 are newly submitted.

Newly submitted claims 16-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 16-22 are directed to a method of accelerating mineral absorption while the originally claimed invention was directed to a composition comprising cyclic carbohydrates and saccharides.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 13-15, drawn to a composition comprising the cyclic tetrasaccharide, ({→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and derivatives thereof).

Group II, claim(s) 16-22 wherein, drawn to a method of accelerating mineral absorption in animals including humans comprising the step of administering the cyclic tetrasaccharide {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and derivatives thereof).

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common technical feature is the cyclic tetrasaccharide, {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and derivatives thereof. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. For example, Kubota et. al. discloses the preparation of the same tetrasaccharide and its use in food and pharmaceutical preparations. (WO 01/90338, Publication Date 11/29/2001; Of record;). English Equivalent, U.S. Patent No. 7,192,746 (Of record) is used *in lieu* of translation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections Withdrawn

In view of the cancellation of claims 1-12, all rejections made with respect to claims 1-12 in the previous office action are withdrawn.

The rejection of claim 14 under section 112, second paragraph in regards to the recitation, "delicious tasting" is withdrawn since said recitation is deleted in claim 14.

The following is a new ground of rejection necessitated by applicants' amendments:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13-15 recite a unit dosage form. Applicant's amendment with respect to the amendments reciting "unit dosage form" herein has been fully considered, but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for applicants' claim a unit dosage composition.

Consequently, there is nothing within the instant specification, which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

The following are new or modified rejections necessitated by Applicant's amendment filed 7/30/07, wherein the limitations in pending claims 13-14 as amended now have been changed, and claim 15 is newly submitted. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, mailed 7/30/07, have been modified and are listed below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 of copending Application No. 10/551,765 in view of Kubolta et. al. (WO 01/90338, Publication Date 11/29/2001; Of record;). English Equivalent, U.S. Patent No. 7,192,746 (Of record) is used *in lieu* of translation.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '765 application claims unit dosage forms of compositions of lipid-regulating agent comprising a cyclic tetrasaccharide represented by the formula {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or its saccharide-derivative(s) as an effective ingredient, and the instant application claims an accelerator for mineral absorption, which comprises an effective ingredient cyclic tetrasaccharide represented by {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof. Note that it is well settled that "intended use" of a composition or product, e.g., "lipid regulating agent", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Thus, claims 13-15 are deemed anticipated by claims 1-16 of the co-pending application.

The disclosure of Kubolta et. al. is discussed below in the 102 rejection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising a dosage form composition comprising the cyclic tetrasaccharide and one of more minerals and yet another compound with mineral absorption promoting action as recited herein since the '765 application claims a composition comprising the tetrasaccharide and Kubolta et. al. discloses compositions comprising minerals and mineral absorbing promoting substances with the tetrasaccharide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 7/30/07have been fully considered but they are not persuasive. Applicants argue that, with respct to claims 13-15, it would not have been obvious from the claims of co-pending application to provide a dosage form containing an amount sufficient for accelerated mineral absorption of the cyclic tetrasaccharide in question, nor to include a mineral compound, nor to include an amount sufficient for promoting substances having a mineral absorption promoting action considering the intended purpose recited in the claims of the co-pending application. However, as discussed above and in the previous office action, intended use is not considered to further limit composition claims. In regards to the amount sufficient for promoting substances having a mineral absorption promoting action, the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, and the burden is on Applicant to show a novel or unobvious difference between

the claimed product and the product of the prior art. It would have been obvious to one of ordinary skill in the art to prepare a composition claimed herein in view of the '765 application and Kubolt et. al. The rejection is still deemed proper and is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation, "derivative" in these claims render claims herein indefinite. The recitations, "derivative" of the compounds are not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "derivative" of compounds herein. One of ordinary skill in the art would clearly recognize that the recitations "{→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof" as well as derivatives of the classes of compounds listed in claims 6 and 8-9 would read on any those compounds having any widely varying groups that possibly substitute the compounds.

Response to Arguments

Applicant's arguments filed 7/30/07have been fully considered but they are not persuasive. Applicants argue that, the applicants definition of the term is given in paragraph 10 of the published application. The cited passage provides that, "'saccharide derivative of cyclic tetrasaccharide' as referred to as an in the present invention means a saccharide where one or more of the same or different glycosyl residues are bound to cyclic tetrasaccharide". This however, is not considered to provide clear definition of the term the recitation, "{→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof". The recitation does not identify or limit which glycosyl residues are encompassed by the term or how many of the glycosyl groups are attached or where they are attached on the cyclic tetrasaccharide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubolta et. al. (WO 01/90338, Publication Date 11/29/2001; Of record;). English Equivalent, U.S. Patent No. 7,192,746 (Of record) is used *in lieu* of translation.

Kubolta et. al. discloses the synthesis of the cyclotetrasaccharide, cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}. (Abstract, Example A-1 to A-5, Columns 55-58). Kubolta further discloses a composition comprising said cyclic tetrasacchirde, (100 parts by weight), mineral, sodium chloride and potassium chloride, magnesium sulfate. (Example B-18, Column 65, lines 20-40). Kubolta further discloses sodium L-ascorbate (which is considered an ascorbic acid derivative), vitamin E and trehalose in composition comprising cyclic tetrasaccharide. (Example B-18, Column 65, lines 20-40). The example provides for a one-bag product mixture (25 grams), which can be dissolved in 150-300 ml water for a fluid diet, which is considered a unit dosage form. Since water is used to dissolve the mineral, sodium chloride, water is considered a substance having mineral absorption promoting action. Kubolta further discloses several examples of compositions comprising said cyclostetrasaccharide and one or more of the ingredients of claims 13-15 herein. (Examples B1-B25; Columns 60-68). Note that, the recitations "an accelerator for mineral absorption", is considered intended uses of the compositions claimed. As discussed above, "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the

same composition comprising the same ingredients in an effective amount, as the instantly claimed.

As such, claims 13-15 are deemed anticipated by Kubolta et. al.

Response to Arguments

Applicant's arguments filed 7/30/07 have been fully considered but they are not persuasive. Applicants argue that, the compositions of claims 13-15 are specifically adapted for the claimed utility and as such are not disclosed or made obvious by Kubota. This argument was found unpersuasive since the compositions disclosed by Kubota are considered capable of achieving the utility of mineral absorption. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). As noted in MPEP (716.02), any differences between the claimed invention and the prior art may be expected to result in some differences in properties. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960). The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, one of ordinary skill in the

art will view that a difference that is to the extent that is really is unexpected is absent. Furthermore, the applicants have made no such comparisons here. (MPEP 716.02).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/15/07

Roy P. Issac
Patent Examiner
Art Unit 1623

S. Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623